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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,761	06/18/2001	Rolando Barbucci	1756	2132

7590 09/24/2003
Walter H Schneider
21530 Beechwood Road
Circleville, OH 43113

EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/24/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,761

Applicant(s)

BARBUCCI ET AL.

Examiner

EVERETT WHITE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 14, 15, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14, 15, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 4, 2003 has been entered.

2. The amendment filed September 4, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

- (A) New Claim 18 has been added.
- (B) Claims 12 and 14 have been amended.
- (C) Comments regarding Office Action have been provided drawn to:
 - (a) 102(b) rejection, which has been maintained and amended;
 - (b) 102(e) rejection, which has been maintained and amended; &
 - (c) 103(a) rejection, which has been withdrawn.

3. Claims 12, 14, 15, 17 and 18 are pending in the case.

4. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

5. It is not clear if Applicants intended for Claim 17 to be canceled or not since Claim 17 was not properly disclosed in the amendment filed by Applicants on July 30, 2003. Clarification of the status of Claim 17 is requested in Applicants next response.

Claim Objections

6. Claim 12 is objected to because of the following informalities: In Claim 12, the term "hemiauccinylated" should be changed to - - hemisuccinylated - -; In Claim 18, line 4, the term "C₂C₆" should be changed to - - C₂-C₆ - -. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 14, the phrase "metal complex of a cross-linked hyaluronic acid derivative according to Claim 18" lacks clear antecedent bases by depending from Claim 18 since Claim 18 does not mentioned a metal complex, which renders Claim 14 indefinite.

8. Applicant's arguments with respect to Claim 14 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

9. Claims 15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Pouyani et al (US Patent No. 5,616,568, already of record).

Applicants claim a hyaluronic acid derivative comprising cross-linking molecules of hyaluronic acid obtained by the reaction of the carboxylic acid groups of hyaluronic acid and a diamine of the formula $\text{NH}_2\text{-A-NH}_2$ wherein A is a linear $\text{C}_2\text{-C}_6$ alkylene chain or a polyoxyalkylene chain of the formula $[(\text{CH}_2\text{-O-CH}_2)_2]_m$ wherein m is an integer from 2-10. Additional limitations in dependent Claim 15 include a pharmaceutical composition comprising the hyaluronic acid derivative of Claim 18.

It is noted that independent Claims 17 and 18 are in the form of a product-by-process claim. The Office considers product-by-process claims as product claims. Process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), supra; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981. Hence, the only passage in Claim 18 relevant toward examination of the claimed invention is "a hyaluronic acid derivative comprising cross-linked molecules of hyaluronic acid" (for example).

The Pouyani et al patent discloses chemically modified hyaluronic acid and cross-linked derivatives thereof (see column 1, lines 7 and 8), which anticipates the hyaluronic acid derivative of instant Claims 17 and 18. Also see column 2, lines 35-38 wherein the Pouyani et al patent set forth the passage "functionalized hyaluronate and its crosslinked derivatives may be utilized in pharmaceutical compositions", which anticipates the pharmaceutical composition of instant Claim 15. Applicants are reminded that a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161.

10. Applicant's arguments with respect to Claims 15, 17, and 18 have been considered but are moot in view of the new ground(s) of rejection.

11. Claims 14, 15, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Prestwich et al (US Patent No. 5,874,417, already of record).

Applicants claim a hyaluronic acid derivative comprising cross-linking molecules of hyaluronic acid obtained by the reaction of the carboxylic acid groups of hyaluronic acid and a diamine of the formula $\text{NH}_2\text{-A-NH}_2$ wherein A is a linear C2-C6 alkylene chain or a polyoxyalkylene chain of the formula $[(\text{CH}_2\text{-O-CH}_2)_2]_m$ wherein m is an integer from 2-10. Additional limitations in the dependent Claims include a cross-linked hyaluronic acid derivative in the form of a metal complex wherein the metal is selected from zinc, copper or iron; and a pharmaceutical composition comprising the hyaluronic acid derivative.

It is noted that independent Claims 17 and 18 are in the form of a product-by-process claim. The Office considers product-by-process claims as product claims. Process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), *supra*; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981. Hence, the only passage in Claim 18 relevant toward examination of the claimed invention is "a

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hyaluronic acid derivative comprising cross-linked molecules of hyaluronic acid" (for example).

The Prestwich et al patent discloses chemically modified hyaluronic acid and cross-linked derivatives thereof (see column 1, lines 12 and 13), which anticipates the hyaluronic acid derivative of instant Claims 17 and 18. The Prestwich et al patent discloses that the hyaluronic acid thereof may be used as an aid in ophthalmic surgery and also as a potential therapy for osteoarthritis in humans, which anticipates the pharmaceutical composition of instant Claim 15. At the last paragraph of column 22, under Example 10, the Prestwich et al patent discloses forming hyaluronic acid gels in the presence of metal ions, wherein the metal ions may be selected as copper and iron, which anticipates the metal complex cross-linked hyaluronic acid of instant Claim 14.

12. Applicant's arguments with respect to Claims 14, 15, 17, and 18 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

13. Claims 12, 14, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prestwich et al (US Patent No. 5,874,417, already of record) in view of Galin et al (US Patent No. 5,944,753, already of record) for the reasons already of record on pages 5-7 of the Office Action mailed October 2, 2002.

Applicants claim a hyaluronic acid derivative comprising cross-linking molecules of hyaluronic acid obtained by the reaction of the carboxylic acid groups of hyaluronic acid and a diamine of the formula $\text{NH}_2\text{-A-NH}_2$ wherein A is a linear $\text{C}_2\text{-C}_6$ alkylene chain or a polyoxyalkylene chain of the formula $[(\text{CH}_2\text{-O-CH}_2)_2]_m$ wherein m is an integer from 2-10. Additional limitations in the dependent Claims include: the hydroxy groups of the hyaluronic acid derivative being sulfated or hemisuccinylated; a cross-linked hyaluronic acid derivative in the form of a metal complex wherein the metal is selected from zinc, copper or iron; and a pharmaceutical composition comprising the hyaluronic acid derivative.

It is noted that independent Claims 17 and 18 are in the form of a product-by-process claim. The Office considers product-by-process claims as product claims. Process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), *supra*; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981. Hence, the only passage in Claim 18 relevant toward examination of the claimed invention is "a hyaluronic acid derivative comprising cross-linked molecules of hyaluronic acid" (for example).

The Prestwich et al patent discloses chemically modified hyaluronic acid and cross-linked derivatives thereof (see column 1, lines 12 and 13), which embraces the hyaluronic acid derivative of instant Claims 17 and 18. The Prestwich et al patent discloses that the hyaluronic acid thereof may be used as an aid in ophthalmic surgery and also as a potential therapy for osteoarthritis in humans, which embraces pharmaceutical composition of instant Claim 15. At the last paragraph of column 22, under Example 10, the Prestwich et al patent discloses forming hyaluronic acid gels in the presence of metal ions, wherein the metal ions may be selected as copper and iron, which embraces the metal complex cross-linked hyaluronic acid of instant Claim 14. The cross-linked hyaluronic acids of the instant claims differ from the cross-linked hyaluronic acids of the Prestwich et al patent by further indicating that the hydroxy groups of the hyaluronic acid are sulfated or hemisuccinylated. The Galin et al patent shows that sulfated hyaluronic acid is well known in the art (see column 6, line 11). Also see example 2 of the Galin et al patent wherein a process step is disclosed whereby heparin (a sulfated polysaccharide) is coupled with a diamine. This process step of Example 2 of the Galin patent embraces the cross-linkage of the sulfated hyaluronic acid of the instant claims since the Galin et al patent teaches the substitution of heparin with sulfated hyaluronic acid. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the hyaluronic acid used to form a cross-linked hyaluronic acid of the Prestwich et al patent with sulfated

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hyaluronic acid, in view of the recognition in the art, as evidenced by the Galin et al patent, that sulfated polysaccharides such as sulfated hyaluronic acid improves the biocompatibility of implants in the anterior chamber of the eye.

14. Applicant's arguments with respect to Claims 12, 14, 15, 17, and 18 have been considered but are moot in view of the new ground(s) of rejection.

Summary

15. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

16. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

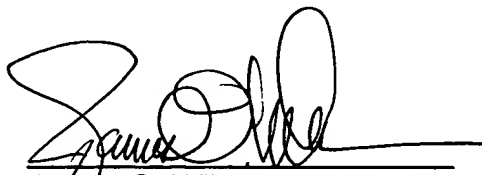
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600